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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,774	PHILLIPS, DAVID B.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *17-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges the amendments received 17 January 2007. Claims 17-22 are withdrawn; claims 1-16 are pending.

Response to Arguments

2. Applicant's arguments with respect to claims 11-16 have been considered but are moot in view of the new grounds of rejection.

3. Applicant's arguments filed 17 January 2007, regarding claims 1-10, have been fully considered but they are not persuasive. In response to applicant's arguments in regards to claim 1, the recitation "for treating neuropathy" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

4. Regarding claim 4, the applicant argues (page 9, "Remarks") "the art cited by the examiner is directed to iontophoretic treatment, rather than treating neuropathy; the drug reservoir feature of the various cited prior art is not necessarily a first and second container with a water-electrolyte solution." The examiner respectfully disagrees. Sage (cited in the previous Non-Final Office Action) does in fact disclose, (Figure 2; col. 4, lines 11-34) "drug reservoir (21) and electrolyte reservoir (23) are part of a common

housing (27). First electrode (22) and second electrode (25) are electrically separated by insulating material (28) in the housing. In this embodiment, the entire housing is made of insulating material, such as plastic. Drug reservoir is capable of holding an ionic compound such as a therapeutic compound, a diagnostic compound and a drug. In many cases, the ionic compounds are ionic liquids, however, the compound may be in the form of a gel or may be contained in the reservoir along with other materials such as porous polymeric structures. For the purpose of the description of this invention, drug reservoir contains a therapeutic liquid (29). This therapeutic liquid does not limit the invention but is intended to be representative of these many possibilities for an ionic compound which can be delivered iontophoretically. Electrolyte reservoir (23) contains electrolyte solution (31). The electrolyte solution may be in the form of a liquid or a gel." This clearly indicates that not only does Sage's device contain a first container and a second container configured to hold a fluid, but also that one of the fluids disclosed is a water-electrolyte solution, as required by claim 4. Furthermore, Haak (also previously cited) discloses, (Figure 1; col. 6, lines 9-13) "In a typical device (10), the drug reservoir (24) contains a neutral, ionized, or ionizable supply of the drug or agent to be delivered and the counter reservoir (25) contains a suitable electrolyte such as, for example, sodium chloride, potassium chloride, or mixtures thereof." Haak therefore also discloses a first and second container configured to hold a fluid, wherein the fluid could be a water-electrolyte solution.

5. Regarding claim 10, the applicant argues, ("Remarks," page 9) "Tapper does not disclose, however, that the voltage is adjusted by the variable resistor based on the

resistance between the first electrode and second electrode." The examiner respectfully disagrees. In a previously cited passage, Tapper discloses "when a load (30) is imposed across the electrodes (10), a steady flow of direct current is permitted to flow from the battery (20) through the primary winding (24), the diode (28), the secondary winding (26), the load (30), and to ground through a variable resistor (32). The variable resistor is used to control the amount of current which is permitted to flow across the load." Since a load is defined as a resistance between two points, and Tapper's Figure 2 shows this load across the two resisters, it is clear that Tapper does disclose adjusting a voltage associated with the asymmetric biphasic signal based on the resistance between the first electrode and the second electrode.

6. The applicant further argues that the Ostrow reference (previously cited) "fails to disclose or suggest propagating an asymmetrical biphasic signal through a first extremity and a second extremity. Ostrow's invention is for is an apparatus with a flexible cuff. Though this single cuff may be capable of being attached to multiple body parts, during operation it may be attached only to a single extremity." The examiner respectfully disagrees. The examiner can find no mention in the Ostrow reference, either in the passage cited by the applicant, or anywhere else, which suggests that the invention is capable of use only in one location. To the contrary, in Figure 1, the nerve stimulation cuff is used on two extremities, as an example, with each electrode set coupled to the main circuitry. Furthermore, Ostrow discloses, (col. 5, lines 24-30) "This system also allows for transdermal drug treatment simultaneously to more than one location where medical attention is needed. In addition, a non-medicated fluid can also

be used to moisten the porous electrodes as an electrolyte, to assist electrical conductivity when the apparatus is being used for purposes other than drug delivery." This passage clearly shows that Ostrow's invention is intended to be used in more than one location.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 7-8, 12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Soykan et al (U.S. 2004/0039417). Regarding claims 1 and 11, Soykan discloses, (par. 0065) "FIG. 1A illustrates equipment used for stimulating in vitro endothelial cells. The Falcon Cell Culture Inserts were then inserted into the holding chamber containing a conductive media. An electrode is placed in the lower chamber and one in the insert. The bottom of the insert is a microporous membrane which allows media and current to pass through while cells remain in the upper chamber. The negative electrode is placed in the side well containing Endothelial Cell Medium-2, without fetal bovine serum, and the cells." The examiner considers this to be a first container and a second container, both being configured to hold a fluid; a first electrode

configured to be in electrical contact with the fluid held by the first container and a second electrode configured to be in electrical contact with the fluid held by the second container. Figure 1A also illustrates (par. 0037) "an array of stimulated cells (3) grown in culture and placed in a testing apparatus (25) and contained in a conductive media (26) for application of various electrical field or electrical current patterns created from stimulatory electrode (1) and return electrode (2)." Soykan further discloses (par. 0038) "FIG. 1B illustrates one pattern of a biphasic stimulation waveform for stimulating cells or tissues for production of tPA. The biphasic waveform (24) as illustrated has an initial cathodic stimulatory phase (4) followed by the anodic stimulatory phase (5), and then a non-stimulatory phase (6)." The examiner considers this to be outputting an asymmetrical biphasic signal; and receiving the asymmetrical biphasic signal at a first electrode and a second electrode. Soykan's invention (par. 0009) "provides an electrical stimulation apparatus for delivering an electrical field or electrical current to the vascular tissue over a predetermined period of time in order to stimulate a cell-initiated thrombolytic peptide response. The electrical stimulation apparatus has an electrical field or electrical current-generating unit (collectively EGU) including a power supply and a control mechanism interconnected with the power supply; and a plurality of electrodes designed to deliver an electrical field or electrical current to the targeted vascular tissue." The examiner considers this to be a controller configured to output an asymmetrical biphasic signal. Though Soykan's device is specifically directed to stimulation of vascular tissue, Soykan also discloses (par. 0006) that complications resulting from a vascular disease that the system and method treat include ischemic

neuropathy. Therefore the examiner considers the system and method of Soykan to be fully capable of treating neuropathy.

9. Regarding claim 7, the examiner considers the system illustrated in 1A to be a first and a second container formed as part of a unitary structure.

10. Regarding claim 8, Soykan discloses, (par. 0056) "In a bipolar electrode, electrodes of both polarities are mounted on a single structure such as catheter or probe and are electrically isolated from one another." The examiner considers this to be a first electrode and a second electrode that are electrically isolated from each other.

11. Regarding claim 12, Soykan discloses (par. 0053) "the electrical field or electrical current is produced by a number of pulses in the range of from 1 to about 1 million pulses with a frequency between about 0.1 Hz to about 20 Hz, and more preferably about 1 Hz to about 10 Hz."

12. Regarding claim 14, the examiner considers both the FBS and the cell-culture medium disclosed by Soykan to be water-absorbing media.

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sage, Jr. (U.S. 5,256,137) or Haak et al (U.S. 6,317,629) in view of Tapper et al (U.S. 4,340,047). For a full discussion of the claimed elements, please see above and the previous Non-Final Office Action.

15. Regarding amended claim 8, the electrodes are isolated from each other in both the Sage and the Haak reference. See Figure 6 (Sage) and Figure 1 (Haak).

16. Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan et al (U.S. 2004/0039417). Regarding claim 13, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

17. Regarding claim 16, Soykan discloses the claimed invention except for the asymmetrical biphasic signal is output at approximately 7.83 Hz. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a signal of approximately 7.83 Hz, since it has been held that discovering the optimum value of a result of effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan et al (U.S. 2004/0039417) in view of Ostrow (U.S. 5,983,134). Soykan fails to teach propagating the output signal through a first extremity and a second extremity. Ostrow however discloses (col. 6, lines 65-68) an electrically conductive applicator pad capable of passing a slow drip liquid drug medium through the skin and surface tissues. The pad forms a cuff that wraps around a body part or limb, and is capable of drug delivery and TENS (transcutaneous nerve stimulation) using iontophoretic and electromagnetophoretic protocols. Ostrow further discloses (col. 5, lines 14-18) "the

multi-modal nature of this apparatus covers a broad spectrum of treatment protocols, including the treating of injuries to soft tissues, as well as arthritis of joints at selected locations of the human and mammalian bodies." Soykan and Ostrow both teach stimulation systems for applying an electric current to the skin of a patient. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Soykan's vascular stimulation system with Ostrow's limb application in order to provide a reduced-irritation electrical signal to treat neuropathy or pain of an extremity at the source of the pain directly.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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